## REMARKS

Claims 1, 2, 6, 7, 12, 13, 15-17, 24 and 27-31 are pending in this application. Claims 2, 6 and 12 are canceled herein. Claims 1, 7, 13 and 15 are amended herein. Claim 7 is amended to depend from claim 1, in view of the cancellation of claim 6. Claims 1, 13 and 15 are amended to address issues raised by the Examiner. Support for the claim amendments is provided by the specification at, e.g., Examples 1-4, and by the claims as filed. Accordingly, no new matter is added by way of these amendments. Applicants respectfully request entry of the claim amendments and reconsideration in view of the following remarks.

It is respectfully submitted that the present claim amendments place all of the pending claims in condition for allowance, without further search or consideration. Therefore, entry of the amendment is appropriate under 37 C.F.R. 1.116, and notification of the allowance of the claims is earnestly solicited. At a minimum, Applicants respectfully submit that the present claim amendments eliminate issues and place the claims in better form for consideration on appeal.

Formal Matters

Applicants thank the Examiner for withdrawal of the rejections under 35 U.S.C. § 102 and/or § 103 over the references of Okihara et al., Hennink et al., and Hakomori et. al.

Rejections under 35 U.S.C. § 112, first paragraph – Written Description

Claims 1, 2, 6, 7, 12, 13, 15-17, 24 and 27-31 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner asserts that the specification does not provide support for polymers/oligomers/co-oligomers having "chiral regions." Applicants respectfully traverse the rejections.

The Applicants respectfully disagree with the Examiner's position, because one of skill in the art would clearly understand from the specification that polymers grafted with oligomers or co-oligomers prepared by polymerization of chiral monomers would contain chiral regions. Nevertheless, to facilitate prosecution, claims 1, 13 and 15 are amended to delete the term "chiral region." As amended, the claims recite water soluble or water dispersible hydrophilic polymers grafted with oligomers or co-oligomers comprising homo-oligomers of L- or D-lactic acid.

Accordingly, Applicants respectfully request that the written description rejections under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph – Enablement

Claims 1, 2, 6, 7, 12, 13, 15-17, 24 and 27-31 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. Specifically, the Examiner asserts that the specification, while being enabling for dextran polymer grafted with lactide, does not reasonably enable all hydrophilic polymers and all oligomers or co-oligomers. Applicants respectfully traverse the rejections, for reasons of record as well as at least the following.

"To be enabling, the specification of a patent must teach those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation' ... Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). MPEP § 2164.01.

The Examiner asserts on page 6 of the Office action that the amount of experimentation needed to practice the full scope of the claimed invention is undue, because "the artisan would have to experiment with a host of chiral monomers from chiral amino acids to chiral acids to chiral compounds for grafting onto any water soluble polymers."

As the Examiner knows, "the test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). MPEP § 2164.06.

As amended, the claims relate to water soluble or water dispersible hydrophilic polymers grafted with oligomers or co-oligomers comprising homo-oligomers of L- and D-lactic acid. Thus, one of skill in the art would not need to experiment with a host of chiral monomers to practice the

invention as claimed. With respect to grafting such oligomers or co-oligomers onto hydrophilic polymers, the specification provides guidance for the preparation of grafted polymers, at, e.g., Examples 1, 2 and 4. In addition, Applicants respectfully submit that conditions for grafting hydrophilic polymers were known to one of skill in the art at the time of the application.

While the scope of disclosure required for enablement varies inversely with the degree of predictability in the art, it is well-settled that even in unpredictable arts, the disclosure of every operable species is not required. *See* MPEP § 2164.03 Based on the starting materials and synthetic routes provided, the synthetic examples prepared, and the rheological and drug release data disclosed, Applicants respectfully submit that the claims, as currently presented, are reasonably enabled.

Accordingly, Applicants respectfully request that the enablement rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejections under 35 U.S.C. § 112, second paragraph

Claim 6 is rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite, because the metes and bounds of the terms "cellulose derivative," and "related copolymers" of poly(lysine) and poly(glutamic acid) are allegedly not defined. Applicants traverse the rejection.

Solely to advance prosecution, and without acquiescing to the Examiner's argument, claim 6 is canceled herein, rendering the rejection moot. Applicants respectfully request the rejection under 35 U.S.C. § 112, second paragraph be withdrawn.

Nonstatutory obviousness-type double patenting

Claims 1, 2, 6, 7, 12, 13, 15-17, 24 and 27-31 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1, 2, and 6-24 of copending Application No. 10/521,369 (US 20070185008). Applicants traverse the rejection.

Applicants respectfully request that the nonstatutory obviousness-type double patenting rejection be held in abeyance until such time as allowable claims are identified, at which time Applicants will submit a terminal disclaimer to obviate the rejection, if necessary.

Objection under 37 C.F.R. § 1.75(c)

The Examiner has objected to claim 2 under 37 C.F.R. § 1.75(c), on the grounds that the Applicants' comment that claim 2 "does not *define* the oligomers of claim 1" (emphasis added) indicates that claim 2 does not further limit claim 1. Applicants respectfully disagree with the Examiner's characterization of the Applicants' remark. Nevertheless, solely to advance prosecution, claim 2 is canceled herein, rendering the objection moot.

Applicants respectfully request that the objection under 37 C.F.R. § 1.75(c) be withdrawn.

## CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 313632001000. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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